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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,048	03/25/2002	Murdo M. Black	DUMM: 009US	2549

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EXAMINER	
VESTAL, REBECCA MICHELLE	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,048	BLACK ET AL.	
	Examiner	Art Unit	
	R. Michelle Vestal	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005 and 28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *various*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendments dated January 18, 2005 and February 28, 2005, which papers have been placed of record in the file.

Claims 1, 7, 8, 10-12 and 14 are amended. Claims 17 and 18 have been cancelled. Claims 1-16 are pending and are examined in this office action.

The drawings have been amended to overcome the objections stated in the first office action.

The title has been amended to more accurately reflect the claimed invention.

All rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,395,504 to Saurer et al, referred to hereafter as "Saurer."

Regarding Claim 1, Saurer discloses a test device for testing of analyte concentration in a fluid to be applied thereto (Col. 1, lines 6-12), the device comprising:

(a) a plurality of sensors on a reel or roll (Col. 2, lines 41-47 and Col. 7, lines 9-12), each of said sensors carrying reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid (Col. 4, lines 15-22), and each of said sensors having a plurality of electrodes (Fig. 2, **16**, **17**), corresponding electrodes of adjacent sensors being connected together by a conductive track on the reel or roll (Col. 5, lines 25-31); and

(b) a meter comprising electronics means for producing a signal output which is dependent on the electrical signal from the said sensors (Col. 7, lines 13-14, 31-36 and 59-64), the meter having contacts which are electrically connected with the said conductive tracks (Col. 7, lines 41-44), and a test area for application of a sample to the sensors (Fig. 6, **34**); wherein the contacts remain in a fixed location relative to the test area when the reel or roll is advanced (Fig. 4, **14** and **15** or Figs. 6 and 7, **32** and Col. 6, lines 3-50).

Saurer teaches the limitations of Claim 2, wherein the meter has contacts which are permanently connected to the said conductive tracks (Col. 7 lines 41-44).

Saurer teaches the limitations of Claim 3, wherein the test device further includes separating means for separating a used sensor from one end of the reel (Col. 7, lines 25-28).

Saurer teaches the limitations of Claim 4, wherein the separating means comprises cutting means for cutting the reel (Col. 7, lines 25-28 and Fig. 12, **53**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saurer in view of U.S. Patent No. 5,228,972 to Osaka et al., referred to hereafter as "Osaka."

Saurer applies to Claim 1, as discussed previously.

Regarding Claim 5, Saurer discloses a test device, wherein a sensor is exposed to permit application of a fluid sample at a test area which is within a housing (Col. 3, lines 61-65).

Saurer does not specifically disclose that the housing has a lid which can be moved to cover the test area.

Osaka teaches a test device, wherein the housing has a lid which can be moved to cover the test area (Fig 12, **29**).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the lid of Osaka into the housing of Saurer because the presence of a lid would prevent exposure of the test sample to environmental elements and would also protect the operator of the device from exposure to the test sample, as taught by Osaka (Col. 14, lines 49-52).

Regarding Claims 6 and 7, Saurer discloses a test device with means to advance the reel or roll to locate a fresh sensor in the test area (Col. 3, line 61-Col. 4, line 4).

Saurer does not specifically disclose that the action of closing a lid causes the reel to advance by means of a ratchet mechanism.

Osaka teaches a test device where the movement of the lid from an open position to a closed position causes the reel to advance to locate a fresh sensor in the test area (Col. 14, lines 11-16).

Osaka also teaches the limitations of Claim 7, wherein movement of the lid causes the reel to advance by means of a ratchet mechanism or "toothed wheels" (Col. 14, lines 22-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the reel advancing means of Osaka into the test device of Saurer because the necessary operations for the measurement of an analyte concentration is simplified and contamination of the blood sample is prevented by incorporating these means, as taught by Osaka (Col. 14, lines 49-52 and 56-64).

Regarding Claim 12, Saurer discloses a test device, comprising a plurality of sensors on a reel or roll (Col. 7, lines 7-12).

Saurer does not specifically disclose that the reel or roll is wound around a rotatable drum.

Osaka teaches the limitations of Claim 12, wherein the reel is wound around a rotatable drum (Fig. 18(A), **22a** and **23a**).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the rotatable drum of Osaka into the test device of Saurer because the drum works in conjunction with a rotary engaging mechanism in order to engage the driving system to advance the reel after a measurement has been made, as taught by Osaka (Col. 13, lines 64-68). Osaka also teaches that this driving mechanism simplifies the necessary operations for the measurement of an analyte

concentration and contamination of the blood sample is prevented by incorporating these means (Col. 14, lines 49-52 and 56-64).

Regarding Claims 10 and 11, Osaka teaches a test device, wherein a container is provided in the housing to receive used sensors (Fig. 4, **20**) and wherein the container is removable from the housing (Col. 1, lines 15-18 and Col. 13, lines 27-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the removable container of Osaka into the test device of Saurer because the handling of the test strip is simplified and hygiene is increased by incorporating such a container into a test device, as taught by Osaka (Col. 14, lines 49-64).

Osaka teaches the limitations of Claim 13, wherein the meter is housed in a housing and the reel is provided in a removable cartridge which is mounted in relation to the housing (Col. 1, lines 15-18 and Col. 13, lines 27-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the removable cartridge of Osaka into the test device of Saurer because the handling of the test strip is simplified and hygiene is increased by incorporating such a cartridge into a test device for analyzing biological fluids, as taught by Osaka (Col. 14, lines 49-64).

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osaka in view of Saurer.

Regarding Claims 14-16, Osaka discloses a cartridge for testing of analyte concentration in a fluid to be applied thereto, comprising a cartridge housing containing a plurality of sensors on a reel (Col. 1, lines 15-18 and Col. 13, lines 27-38), each of said sensors carrying reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid (Fig. 11, **3** Col. 14, lines 30-32); the cartridge having a test area to make contact with corresponding electrical contacts on a meter (Fig. 11, **20** and Col. 12, line 54-Col. 13, line 25), said test area being for application of a sample to the sensors (Col. 14, lines 30-32) and said test area being in fixed relation to said cartridge housing (Col. 13, lines 40-51); wherein when the cartridge is mounted in a meter with electrode contacts of the meter touching at said test area (Col. 12, line 54-Col. 13, line 25), said contacts will remain at a fixed distance from the test area when the reel is advanced (Fig. 12, **28**); wherein the cartridge further includes a mechanism for unwinding and advancing the reel when the cartridge is mounted in the housing of a test device (Col. 19, lines 20-26 and 49-54); and wherein the cartridge further includes storage means for storing used sensors (Col. 13, lines 52-56 and Fig. 10, **23**).

Osaka does not disclose expressly that the sensors have a plurality of electrodes, corresponding electrodes of adjacent sensors being connected together by a conductive track on the reel.

Saurer discloses a plurality of sensors on a reel or roll (Col. 2, lines 41-47 and Col. 7, lines 9-12), each of said sensors carrying reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid (Col. 4, lines 15-22), and each of said sensors having a plurality of electrodes (Fig. 4, **20**, **21** or Fig. 6, **32**), corresponding electrodes of adjacent sensors being connected together by a conductive track on the reel or roll (Col. 6, lines 3-50).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include conductive tracks or electrodes on the sensor reel of Saurer in the cartridge of Osaka because integration of the conductive tracks on the sensor reel ensures good electrical contact between the sample, the reagent means and the meter. The use of a "fresh" set of electrodes for each measurement also eliminates the need to clean the electrode surface of Osaka, which may become contaminated by sample or calibration solution upon contacting the reagent layer.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saurer and Osaka as applied to claim 5 above, and further in view of U.S. Patent No. 5,525,297 to Dinger et al., referred to hereafter as "Dinger."

Saurer and Osaka apply to Claim 5, as discussed previously.

Saurer discloses a test device with means to advance the sensor reel or roll so that a fresh sensor is presented in the test area (Col. 6, lines 45-50) and means to separate a used sensor from one end of the reel or roll (Col. 4, lines 4-6).

Saurer does not specifically disclose the presence of a lid, the operation of which affects the means of advancement or separation.

Dinger teaches the limitations of Claim 8, wherein closure of the lid causes the separating means to operate to separate a used sensor from one end of the reel (Col. 4, lines 16-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the lid of Dinger into the test device of Saurer and Osaka because such an arrangement allows better control of the advancement of the cutting blade and requires less physical exertion in severing the used sensor from the reel (Col. 2, lines 17-42).

Regarding Claim 9, Osaka discloses a test device with a lid, wherein the lid is pivotally mounted in relation to the housing and pivoting of the lid in one direction causes the reel to advance so that a fresh sensor is presented in the test area (Col. 14, lines 11-16).

Osaka does not specifically disclose that pivoting of the lid causes separation of the sensor from the end of the reel.

Dinger teaches a test device where pivoting of the lid causes separation of the sensor from the end of the reel (Col. 4, lines 16-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the functions of the lid of Dinger and the lid of Osaka into the test device of Saurer because the combination of these elements simplifies the necessary operations for measuring the concentration of an analyte, as taught by Osaka (Col. 14, lines 56-57). Furthermore, making elements integral in an apparatus has been held to be obvious (In re Wolfe 116 USPQ 443).

Response to Arguments

Applicant's arguments regarding amended claim 1 have been fully considered but they are not persuasive. Saurer discloses in figure 4 a plurality of sensors on a reel comprising a test area for application of a sample to the sensors (Fig. 4, **35** and **36**) and wherein the contacts (Fig. 4, **14** and **15**) remain in a fixed location relative to the test area when the reel is advanced (Col. 6, lines 9-16 "to make it possible to ensure a sliding contact with the connecting means of the measuring apparatus"). In another embodiment, Saurer discloses in figures 6-9 a plurality of sensors on a reel comprising a test area for application of a sample to the sensors (Fig. 6, **34**) and wherein the contacts (Fig. 6, **32**) remain in a fixed location relative to the test area when the reel is advanced (Col. 6, lines 23-50).

Applicant's argument that claims 2-13 depend from claim 1 and are therefore novel and non-obvious over the cited references is not persuasive for the reasons cited regarding claim 1.

Applicant's arguments with respect to claims 14-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michelle Vestal whose telephone number is (571) 272-0524. The examiner can normally be reached on Monday-Friday, 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmv /rmv
May 13, 2005

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